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(54) Method and Apparatus for Applying High Frequency Extrathoracic Induced Breathing

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The present invention relates to a method and apparatus for high frequency respiration, and more particularly for improved ventilation and/or airway clearance of a patient by extrathoracic compression and expansion.

There have been a number of papers describing induced respiratory ventilation at high frequencies, i.e., 23 to 40 Hz, through an endotracheal tube, as described, for instance, in D. J. Bohn et al in an article entitled "Ventilation by High-Frequency Oscillation", J Appl Physiol: Respirat Environ Exercise Physiol 1980:48:710-716, and in W. J. Butler et al in an article entitled "Ventilation by High-Frequency Oscillation in Humans", Anesth Analg 1980: 59:577-584.

The methods described in these articles as well as other experiments with high frequency ventilation techniques, include supplying a continuous flow of fresh gas to the endotracheal tube by way of the mouth with superimposed oscillations produced by a piston pump. The systems include the use of frequencies of oscillation ranging up to 30 Hz. It was thought, however, that the pulmonary gas exchange was caused as a result of increased diffusion since in most cases the methods resulted in small oscillatory tidal volumes. It has been found, however, that any process which involves an endotracheal tube passing in the airway for the purpose of inducing high frequency ventilation may cause some discomfiture and certainly temporary loss of speech. The use of a mouthpiece for such purposes can cause gagging.

Extrathoracic respirators, particularly cuirass respirators, have been developed to assist in the normal breathing patterns of a patient having various respiratory

diseases, such as poliomyelitis. A history of these devices is provided in an article by C. H. M. Woollam entitled "The Development of Apparatus for Intermittent Negative Pressure Respiration", (2) 1919-1976, published in "Anaesthesia", 1976, Volume 31, pages 666-685. These devices have been developed in order to provide normal respiratory assistance at frequencies below 20 cycles per minute or 0.33 Hz.

An apparatus has been described in relation to clearing airway obstructions due to retained secretions by utilizing an external thoracic vibrocompressor. This vibrocompressor, which is described in an article entitled "Chronic Bronchial Asthma and Emphysema" written by Gustav J. Beck, M.D. and published in "Geriatrics", June 1966, comprises using a cuirass in the form of a canvas belt supporting a vinyl bladder and adapted to cover the lower thorax and upper abdomen. An airflow is provided during expiration only, which emanates from a compressor. This airflow is passed over a vibrator operating at 1800 cycles per minute or 30 Hz, thus transmitting a vibration to the belt or cuirass. An actuating means is provided to initiate the compressor on the patient's own expiration.

It is an aim of the present invention to provide a method and apparatus for providing ventilation by inducing a high frequency vibration or oscillation to the air column in a patient's airway in order to induce artificial breathing and, therefore, gas exchange of air, oxygen, anesthesia gases, aerosols, etc. It is also an aim of the present invention to provide improved clearance of the airway in a patient, due to lodged secretions within the airway.

A method in accordance with the present invention

comprises the steps of applying extrathoracic compression and expansion at a frequency of between 1 and 20 Hz and a maximum peak pressure of 120 cm. of water to thereby provide a tidal volume at the mouth of between 0.3 ml/kg to 3 ml/kg. the total volume being smaller at higher frequencies.

An apparatus in accordance with the present invention comprises an apparatus for providing induced breathing to a living body comprising expansion and compression means for applying a cyclical extrathoracic compression and expansion to said living body, operating means communicating with a source of power for operating said expansion and compression means at a cyclical frequency of between 1 Hz and 20 Hz at a maximum pressure to the thorax of 120 cm. of water to thereby provide a tidal volume at the mouth of between 0.3 ml/kg to 3 ml/kg with the tidal volume decreasing as the frequency increases.

An apparatus in accordance with a more specific embodiment of the present invention comprises a flexible band adapted to be adjustably secured about the thorax of the body to be treated and at least a pair of resilient expandable bladders provided on the interior of the band and adapted to be expanded at least against the rib cage of the body. Conduit means communicate the bladders to a fluid source. Reciprocating pump means are associated with the fluid source for alternatively supplying a fluid under pressure through the conduit means to the expandable bladders and withdrawing the fluid. The pressures in the bladders range between -10 cm. of water and 120 cm. of water. The reciprocating pump means are adapted to provide reciprocating cycle frequency of between 1 and 20 Hz and have an amplitude such as to provide a tidal volume at the

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mouth of the body of 0.3 ml/kg to 3 ml/kg inversely proportional to the frequency.

During tests conducted on paralyzed dogs at frequencies of 3, 5, 8 and 11 Hz, peak pressures applied at the bladders ranged from 30 to 230 cmH_2O. This produced swings of esophageal pressure as high as 18 cmH_2O and peak oscillatory airflow ranging from 0.7 to 1.6 L/sec. Oscillatory tidal volume declined with increasing frequency and ranged from a mean of 61 to 45 ml. After 30 min. of application of this extrathoracic induced breathing, arterial blood gases revealed a mean $PaCO_2$ of 29.3 mmHg at 5 Hz, 35 mmHg at 3 Hz, 36 mmHg at 8 Hz, and 51 mmHg at 11 Hz. Mean PaO_2 improved from ventilator control values at 3 Hz, remained unchanged at 5 and 8 Hz, and declined at 11 Hz.

It has been discovered that such high frequency ventilation in unintubated human beings provides satisfactory ventilation and could improve gas exchange.

Finally, by providing this high frequency ventilation by chest wall compression and expansion, trauma is avoided in the airway as well as improving the patient's comfort and avoidance of any tubes within the airway.

It has also been found that by providing extrathoracic compression and expansion in the higher ranges of the high frequency range, i.e., from 8 to 20 Hz, improved mucous clearance has been achieved in patients suffering from lung disease characterized by mucous hypersecretion.

In healthy subjects, the quantity of tracheobronchial mucus is small, and ciliary mechanisms are adequate to maintain clearance. In patients with lung disease characterized by mucous hypersecretion, cough becomes an additional clearance mechanism. If the mucous overload becomes too great

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for these two mechanisms, then the result is an accumulation of secretions.

The use of physiotherapy or mechanical methods of augmenting clearance has been studied. The available literature shows that chest physiotherapy, such as percussion, postural drainage and encouragement to cough, has been shown to improve clearance of radio-aerosol deposited in the tracheobronchial tree in patients with chronic obstructive bronchitis. In another study with similar patients, it was demonstrated that postural drainage, vibration at 12-16 Hz, percussion at 5 Hz and shaking at 2 Hz for 20 minutes plus encouragement to cough, resulted in a significant increase of secretions from the central, intermediate and peripheral lung regions compared to a control run. On the other hand, vibration alone (41 $\pm$ 5 Hz; 2 mm amplitude) by means of an electrically driven pad applied to patients with chronic bronchitis for 1 hour, was shown to have no effect (D. Pavia et al, "A Preliminary Study of the Effect of a Vibrating Pad on Bronchial Clearance", Amer Rev Resp Dis 1976; 113:92-6).

By using the method of the present invention, it has been observed that with chest wall high frequency compression, the peak expiratory flow rate was greater than the peak inspiratory flow rate. This has been found useful in helping to clear mucus out of the tracheobronchial tree, especially when higher peak expiratory linear velocities at the air-mucous interface occurs during oscillation. Furthermore, it has been shown that when sputum is subjected to high frequency oscillation in the range of 3 to 17 Hz, its viscosity is reduced. This tends to facilitate the removal of airway mucus, either by increased airflow interaction or by enhancement of ciliary clearance.

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Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of illustration, a preferred embodiment thereof, and in which:

Figure 1 is a schematic view showing a patient in a supine position to which an extra-thoracic band is mounted;

Figure 2 is a perspective view, partly broken away, of an embodiment of the extra-thoracic band;

Figure 3 is a vertical cross-section taken through line 3-3 of Figure 2;

Figures 4A to 4D are graphs illustrating various tests at different frequencies within the range; and

Figure 5 is a graph plotting a carbon spot test using the method in accordance with the present invention compared with conventional methods.

Referring now to the drawings, there is shown a band or cuff 10 made of a strip of canvas roughly 9 cm. wide and approximately 120 cm. long. The strip of canvas 12 is provided on the internal side thereof at the end 14 with a large strip of "Velcro"* 16. At the other end 18 of the strip 12 is a cooperating strip of "Velcro" 20 on the outside of the canvas strip. Centrally of the cuff 10 are a pair of double wall chambers 22 and 24 in which are provided rubber or the like bladders 26 and 28. Each bladder in the present embodiment is 12.5 cm. by 27 cm. Communicating with each bladder is a tube 30 having an internal diameter of 1.27 cm.. connected to a molded Y connector 32 which in turn

* "Velcro" is a registered trade mark of Velcro S.A.

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communicates with a conduit in the form of a flexible tube 34 to a reciprocating pump 36. The reciprocating pump is of the conventional type. In the present embodiment, the pump is driven by a variable speed DC motor which has a frequency control. The pump must be large enough to provide a reciprocating cycle of expansion of the bladders 26 and 24 and contraction thereof in frequencies of between 1 and 20 Hz with peak pressures of 120 cm. of water.

Clinical tests have been made on dogs, and these will now be described.

Six dogs weighing between 23 and 34 kilograms were anesthetized and were placed supine, and a cuff 10 was placed around the thorax of each dog with each bladder 24 and 26 positioned on respective sides of their rib cage and with the caudad border of the cuff 10 at the level of the xiphisternum. The tubing 34 was connected to a piston pump. The piston pump consisted of a commercial air compressor pump having two pistons in parallel. The valves of the pump were rearranged so that the piston simply drove air in and out. The pump was driven by a 3 horsepower variable speed DC motor which had a frequency control (maximum frequency of 17 Hz). The DC motor had a small pulley connected by a belt to a larger pulley which drove the piston. The larger pulley also acted as a fan to cool the piston pump.

The cuff 10 was partially inflated by a bias pressure. The bladders 24 and 26 each were provided with small leak outlets, and air was pumped into the bladders at 15 to 20 liters per minute providing a pressure of 3 cm. of H_2O. In addition to this bias pressure, the pressure was oscillated by the pump. The variable leak was regulated so that on withdrawal stroke of the piston, a slightly negative

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cuff pressure (Pcuff) developed. This served to partially deflate the cuff 10 and allow the compressed thorax to expand normally, thereby inducing inspiratory airflow. Tidal volume at the mouth, whether spontaneous (Vts) or oscillatory (Vto) was assessed by integrating flow measured by a screen pneumotachometer (Hans Rudolf No. 4700) with a Validyne pressure transducer ($\pm$ 2 cmH_2O) attached to a 10 mm internal diameter endotracheal tube. The same attachments were used for the calibration of the oscillatory tidal volume (Vto) at oscillatory frequencies ranging from 0.6 to 16 Hz. The data was recorded on a Hewlett Packard recorder model 7758A. During calibration, the other end of the pneumotachometer was connected through a tubing, 7 cm. by 2.54 cm., into a rubber stopper of a 4 liter airtight glass bottle. To measure pressure changes in the bottle, a 10 cm. long catheter having a diameter of 0.94 cm. was inserted through the rubber stopper with its other end connected to the Validyne pressure transducer ($\pm$ 50 cmH_2O) which had a known flat amplitude response to 40 Hz. The size of the bottle and the connecting tube were selected so that minimal resonance would occur over the entire range of frequencies used.

For oscillating calibration, the ratio of integrated tidal volume to the reference tidal volume (yielded by the peak pressure variation in the glass bottle) at each frequency was used as a correction factor. This was found to be 1.00 at 0.6 Hz, 1.38 at each of 3 and 5 Hz, 1.05 at 8 Hz, 0.80 at 11 Hz, and 0.70 at 16 Hz.

For flow calibration, since the piston pump generated a nearly perfect sinusoidal flow, tidal volume and maximum flow are related by

$$\dot{v}\ max = \pi f\ Vt.$$

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Thus, a correction factor for peak flow measurements at a given frequency may be obtained by taking the ratio

$$\frac{\dot{V}\text{ max measured at that frequency}}{\dot{V}\text{ max reference}}.$$

Esophageal pressure (Pes) used as a reflection of pleural pressure was calibrated by oscillating the pressure in a sealed bottle by $\pm$ 10 cmH_2O with the piston pump at different frequencies. A 5 cm. balloon filled with 0.5 cc. air with 100 cm. of PE 200 tubing was placed in the bottle and led out to 267 B Hewlett Packard pressure transducer. The pressure swings were compared with those of another reference 267 B pressure transducer which had short wide bore tubing leading directly into the bottle. The frequency response was flat to 7 Hz. At 11 Hz ΔPes/ΔP reference was 0.9 and Pes lagged by 24 degrees. While it is recognized that at high frequency there would be a damping effect by the mediastinum and esophagus, nevertheless it was felt that Pes would provide at least an underestimation of the pressures transmitted by the cuff into the thorax. In addition, in the supine position the change in esophageal pressure may not provide an accurate measurement of mean pleural pressure change depending on the position of the balloon in the esophagus.

In six paralyzed dogs, ventilatory support was affected by the following. Ventilation at room temperature was supported for 30 minutes by a Harvard volume ventilator delivering tidal volumes of 10 ml/Kgm at 12/min. At the end of each of these periods, control arterial blood gases were measured (Instrumentation Laboratories - 813). The Harvard ventilator was then disconnected and alternated with the cuff 10 for 30 minutes each at frequencies of 5, 8, 3 and 11

Hz. The cuff pressure (Pcuff) was measured, and the variable leak was adjusted so that on the withdrawal stroke of the piston, a slightly negative cuff pressure (Pcuff) occurred. In order to minimize dead space, there were no attachments on the endotracheal tube. Arterial blood gases were measured after 20 and 30 minutes at each frequency. Thereafter, the pneumotachometer was connected to the end of the endotracheal tube and flow and volume were measured. While measuring oscillatory tidal volume (Vto), the cuff oscillations were suddenly discontinued, allowing a measure of that change in volume to paralyzed functional residual capacity (FRC). This change in FRC (ΔFRC) provided a measurement of how far below FRC the extrathoracic system was being applied. In two dogs, cardiac output was measured by the thermo-dilution technique using a Swan Ganz catheter. The cardiac output during conventional mechanical ventilation was compared with that produced with the cuff 10 at different frequencies. In four dogs, quasistatic deflationary pressure volume measurements of the lung and chest wall were made by electrically integrating flow starting at a transpulmonary pressure (P_{TP}) of 25 cmH_2O (TLC) after delivering at least 3 large inflations prior to each measurement.

Two dogs were initially kept anesthetized and not paralyzed. While the dogs continued to breathe spontaneously, induced respiration with the cuff 10 was applied at 5 and 11 Hz and 30 minutes each with each application preceded by 30 minutes of spontaneous ventilation without the cuff 10. Arterial blood gases were measured at the end of each 30 minute period. In one dog with the cuff 10 at 5 Hz, arterial blood gases were obtained every 10 minutes. Thereafter, the pneumotachometer was attached, and Vto, Vts and the

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frequency of spontaneous ventilation (fs) were obtained. Spontaneous minute ventilation ($\dot{V}_{ES}$) was calculated as the product of Vts and fs.

In Figures 4A to 4D, the mean results of Pcuff, Pes, peak flow and Vto are given at 3, 5, 8 and 11 Hz in the paralyzed dogs. On the forward stroke of the piston, the mean peak Pcuff ranged from 80.4 cmH_2O (gauge) at 5 Hz to 102.8 cmH_2O at 11 Hz. On the back stroke of the piston, the variable leak was adjusted so that mean peak Pcuff ranged from -7.9 cmH_2O at 3 Hz to -28.3 cmH_2O at 11 Hz. This negative Pcuff allowed the chest wall of the dogs to recoil back towards their paralyzed FRC with minimal impedance. As an estimation of the pressures transmitted into the thorax, the mean peak expiratory Pes ranged from 7.8 cmH_2O at 3 Hz to 10.6 cmH_2O at 11 Hz. The mean peak inspiratory Pes ranged from -2.4 cmH_2O at 3 Hz to -6.9 cmH_2O at 8 Hz. The mean peak swings in Pes (ΔPes) ranged from 10.2 to 17.3 cmH_2O at 3 and 8 Hz respectively.

The peak flows produced at the mouth were significantly greater on expiration than inspiration ($p < .005$) at 5 and 8 Hz. They were also greater on average at 3 and 11 Hz but this did not attain statistical significance. The mean expiratory peak flow ranged from .70 to 1.61 L/sec. The mean Vto produced at the mouth was maximal at 3 Hz, that is, 61.0 ml, and decreased progressively with frequency: 53.3 ml at 5 Hz, 47.9 ml at 8 Hz, and 45.1 ml at 11 Hz.

The mean PaO_2 achieved 20 and 30 min. post onset of the cuff 10 was slightly higher than the control ventilator PaO_2 at 3 Hz. At 5 and 8 Hz the PaO_2 changed little from control, whereas at 11 Hz the PaO_2 declined progressively. The mean $PaCO_2$ at 3 Hz declined at 20 and 30 min. from a mean

control value of 41 to a mean of 34 and 35 mmHg respectively, and at 5 Hz from 35 to 30 and 29 mmHg respectively. At 8 Hz there was a minimal change from 39 to 36 and 36 mmHg respectively, whereas at 11 Hz there was a progressive increase in $PaCO_2$ from 35 to 47 and 51 mmHg respectively.

In the two paralyzed dogs where cardiac output was measured, there was no change between conventional ventilation and the cuff 10 at the different frequencies.

In the two dogs where the cuff 10 was applied at 5 and 11 Hz for 30 minutes while spontaneous ventilation was occurring, in all cases $\dot{V}_{ES}$ decreased while the $PaCO_2$ changed little. The decreased $\dot{V}_{ES}$ occurred mainly as a result of a decreased Vts while fs changed variably.

The next example was made in order to illustrate the application of the extrathoracic high frequency compression and expansion system to improve the clearance of mucus out of a tracheobronchial tree. It was discovered that higher peak expiratory linear velocities occurred during oscillation at the air-mucous interface. Furthermore, it has been shown that when sputum is subjected to high frequency oscillation in the range used herein, that is, between 3 and 17 Hz, its viscosity is reduced. This would tend to facilitate the removal of airway mucus, either by increased airflow interaction or by enhancement of ciliary clearance.

Nine random-source dogs 25-35 kg. were anesthetized. They were intubated with a shortened No. 10 endotracheal tube and placed supine. A cuff 10 was placed around the thorax of the dogs with the two bladders 24 and 26 positioned on each side of the rib cage and with the caudad border of the cuff at the level of the xiphisternum. The cuff was partially inflated by a bias pressure (air flowing into the cuff at

15-20 L/min. having a variable small leak so as to not over-compress the dog's thorax). Around this bias pressure, the cuff pressure (Pcuff) was oscillated by the pump. The variable leak was regulated so that on the withdrawal stroke of the piston, a slightly negative cuff pressure (Pcuff) developed. This served to partially deflate the cuff and allow the compressed thorax to recoil back towards FRC, thereby causing inspiratory airflow. The setup enablod tidal volumes of 25-100 cc. at frequencies from 3-17 Hz.

Tracheal mucous flow was observed by direct bronchoscopic visualization. A drop (5-10 μl) of a suspension of carbon (Animal Charcoal, Sigma) in saline was placed on the lower tracheal mucosa just above the carina. The leading edge of the spot was located by advancing the bronchoscope until it just passed out of view. The position of the bronchoscope vis-à-vis the endotracheal tube was noted and the bronchoscope withdrawn. After a period of time, the bronchoscope was reintroduced, the leading edge of the carbon spot relocated, and the difference calculated. The mucous clearance rate was then computed as the cephalad projection of distance traveled (in case of spiral motion) divided by the time elapsed. For the measurement of tracheal mucous clearance rate during extrathoracic induced breathing, the bronchoscope was introduced immediately before and after rather than during the period of oscillation.

In three dogs, the variation in tracheal mucous clearance rate (TMCR) as a function of location within the trachea was observed. In randomized order, clearance rates in intrathoracic trachea were compared with clearance rates in extrathoracic trachea for both spontaneous breathing and for extrathoracic induced breathing at frequencies from 3 to

13 Hz. No systematic intratracheal variation in clearance rate was observed in either spontaneous breathing. As a consequence, in the other dogs studied, only intrathoracic tracheal clearance was studied.

The dependence of TMCR on applied frequency was investigated in nine dogs in total. Extrathoracic induced breathing enhanced TMCR over that observed during spontaneous breathing at each frequency tested except 3 Hz. The enhancement of TMCR was sharply dependent on frequency, peaking at 13 Hz. The control TMCR during spontaneous breathing averaged 8.2 $\pm$ 5.6 (SD) mm/min; the mean rate at 13 Hz was 27.6 $\pm$ 13.8 mm/min, or 340% control. This difference was significant ($p < .001$).

The reproducibility of the method was examined in two ways. One dog was studied on two occasions, separated by two days. Similar baseline clearance rate and frequency dependence were observed. In a second dog, two frequency runs were performed at two different levels of anesthesia. This was accomplished by giving a bolus of pentothal followed by infusion at 2 mg/kg/min during the second run instead of the usual 1 mg/kg/min. This resulted in a decrease in baseline TMCR, but no alteration in the slope of the frequency response, as shown in Figure 5.

Finally, the necessity for oscillatory airflow to occur and not just chest wall vibration in order to enhance clearance rates was investigated in three dogs by blocking the endotracheal tube during the two minutes of extrathoracic induced breathing. In each of the three experiments, no enhancement of clearance was observed with this maneuver. There was, in fact, a subsequent inhibition of tracheal clearance that persisted for at least one-half hour when this

maneuver was performed.

These experiments suggest that high frequency extrathoracic induced breathing might be of great potential benefit as a mode of chest physiotherapy. This might relate to the fact that the vibration is not localized but spread over the chest walls such as to provide significant airflow. The airflow seems to be important in moving secretions. Further, the frequency range for most effective enhancement of clearances is between 11 and 15 Hz, coinciding with the natural range of cilia beat frequencies, that is, in patients where the cilia are functioning normally.

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The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. An apparatus for providing extrathoracic induced breathing in a body comprising a flexible band adapted to be adjustably secured about the thorax of the body to be treated, and at least a pair of resilient expandable bladders provided on the interior of the band and adapted to be expanded against the rib cage of the body, conduit means communicating the bladders to a fluid source, reciprocating pump means associated with the fluid source for alternatively supplying a fluid under pressure through the conduit means to the expandable bladders and withdrawing the fluid, the pressures ranging between -10 cm. of water and 120 cm. of water within the bladders, the reciprocating pump means adapted to provide a sinusoidal reciprocating cycle frequency of between 1 and 20 Hz and having an amplitude such as to provide a tidal volume at the mouth of the body of 0.3 ml/kg and 3 ml/kg which decreases as frequency increases.

2. An apparatus as defined in claim 1, wherein the reciprocating cycle is applied at a frequency of between 2 and 11 Hz.

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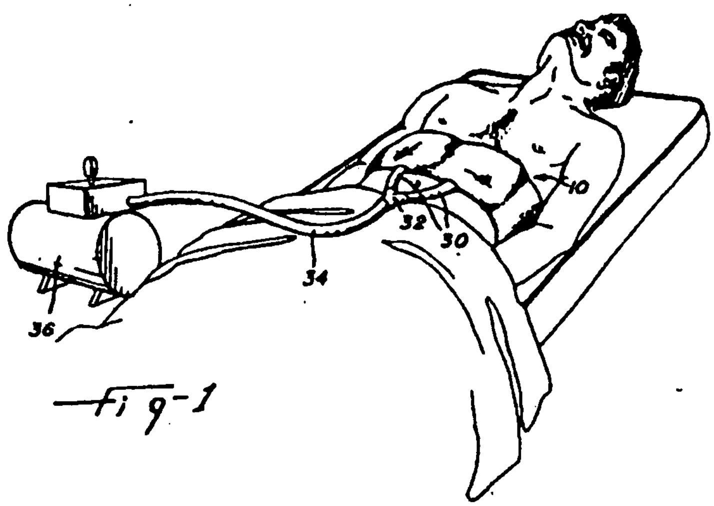
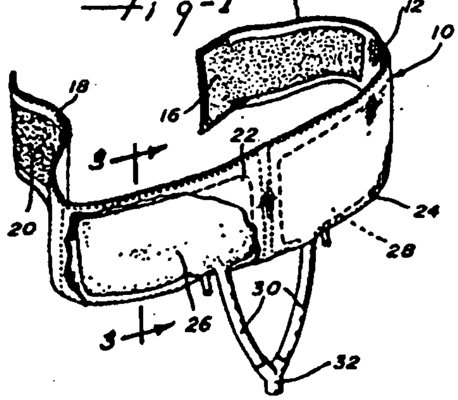


Fig-1

Fig-1



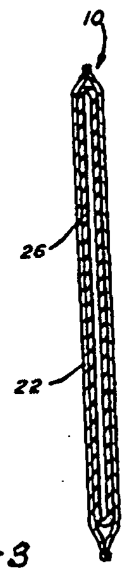


Fig-3

Fig-2

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3-2.

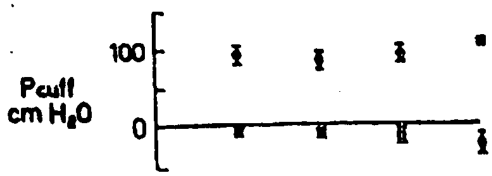

Fig-4a

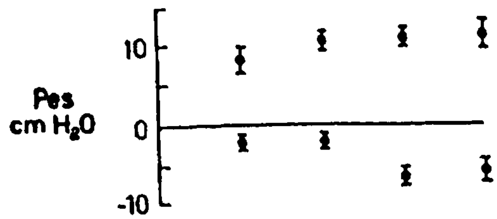

Fig-4b

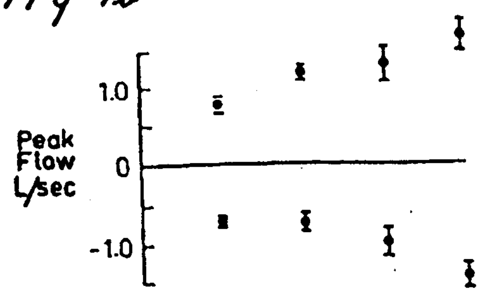

Fig-4c

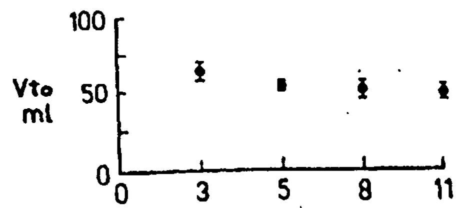

Fig-4d

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3-3

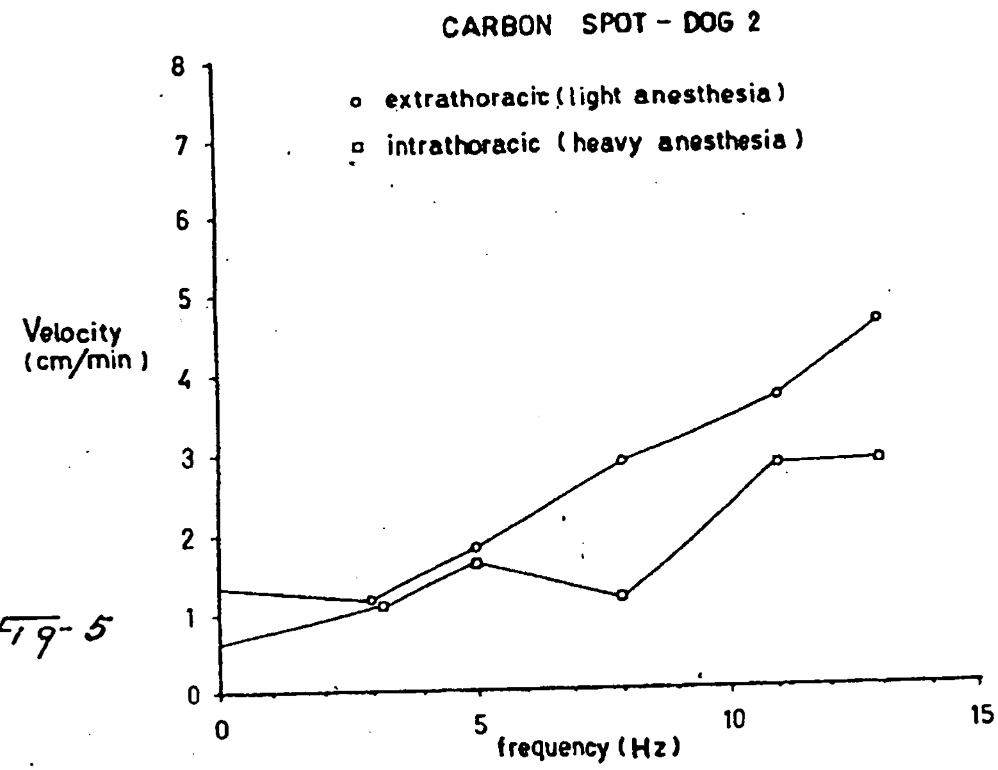

Fig-5

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